



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/672,100

09/26/2003

Erwin R. John

50124/01101

7113

<sup>7590</sup>  
FAY KAPLUN & MARCIN, LLP  
Suite 702  
150 Broadway  
New York, NY 10038

12/10/2008

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                       |  |
|------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/672,100  | <b>Applicant(s)</b><br>JOHN, ERWIN R. |  |
|                              | <b>Examiner</b><br>LAURA A. BOUCHELLE | <b>Art Unit</b><br>3763               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 36-46 and 53-55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-35, 47-52 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-4, 6, 9, 10, 12-19, 21, 23, 27, 28, 30-35, 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al (US 2005/0038371) in view of Suffin (US 6622036). Reich discloses a method comprising the steps of inserting a first 13 and second 12 conduit into a patient's body, the conduits are open to a portion of the patient's CNS with direct access to CSF, the first conduit opens to a first reservoir 40 of material to be introduced into the CSF and the second conduit opens to drain CSF permanently withdrawn from CNS (page 2, paragraph 0014). The device treats neurological conditions that may be brought on by a chemical imbalance by increasing the turnover rate of the CSF thereby removing CFS having a high level or deleterious chemicals and replacing it with CSF of a normal concentration. The second conduit opens into the peritoneal cavity and the flow of CSF is controlled by a second pump 24. The intracranial pressure of the patient is monitored by a sensor 29.

3. Claims 1, 20 differ from Reich in calling for the step of detecting and analyzing brain activity of a patient. Claim 2, 24 differ in calling for the brain activity to be detected using QEEG. Claim 49 calls for the brain activity to be compared to normal brain activity. Suffin teaches a method for assessing brain imbalances comprising the steps of analyzing brain activity to determine an imbalance using QEEG to determine normal from abnormal brain activity (abstract). Determining abnormal brain activity inherently includes the step of comparing the brain activity to normal brain activity. Therefore, it would have been obvious to one of ordinary

Art Unit: 3763

skill in the art at the time of invention to modify the method of Reich to include the steps of monitoring brain activity using QEEG as taught by Suffin to determine normal from abnormal brain activity so that a medical professional can evaluate the treatment method.

4. Claims 5, 11, 22, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Suffin as applied to claims 1, 20 above, and further in view of Harper et al (US 6436091). Claims 5, 11, 22, 29 differ from the teachings above in calling for the pump to be an osmotic pump. Harper teaches a method for delivering a pharmaceutical agent comprising an osmotic pump that allows the infusion rate to be adjusted (Col. 2, lines 50-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the pump of Reich in view of Suffin to be an osmotic pump as taught by Harper so that the infusion rate of the device can be adjusted.

5. Claims 7, 8, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Suffin as applied to claims 1, 20 above, and further in view of Brengle et al (US 20030130645). Claims 7, 8, 25, 26 differ from the teachings above in calling for the device to include a plurality of chambers and a plurality of pumps. Brengle teaches a device of delivering medical fluid comprising a plurality of chambers controlled by a plurality of pumps so that the treatment can be tailored to fit the patient's needs (Page 1, paragraph 0010). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device above to include a plurality of chambers and a plurality of pumps as taught by Brengle so that the treatment can be tailored to fit the patient's needs.

***Response to Arguments***

6. Applicant's arguments filed 8/27/08 have been fully considered but they are not persuasive. Applicant argues that a combination of detecting brain activity with Reich would change the principle operation of Reich. The examiner disagrees. The examiner agrees with Applicant that Reich discloses that the rate of infusion and withdrawal of fluids is affected by sensors that determine if the patient is in an upright or supine position. In broader terms, Reich discloses that a sensor is used to determine a condition of a patient that requires a change in the flow rate into or out of the CSN. Suffin merely teaches a different type of sensor to determine the required treatment. The examiner believes that it would be obvious to use any type of known sensor to determine if the patient requires infusion or withdrawal and at what rate.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle  
Examiner  
Art Unit 3763

/Laura A Bouchelle/  
Examiner, Art Unit 3763